

GOVERNMENT OF THE DISTRICT OF COLUMBIA
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Maker of Opioid Addiction Treatment Drug Suboxone Accused of Conspiring to Keep Monopoly Profits

WASHINGTON, D.C. – Attorney General Karl A. Racine and 35 other state attorneys general have filed an antitrust lawsuit against the manufacturers of Suboxone, a prescription drug used to treat opioid addiction. The suit alleges that the manufacturers harmed consumers by engaging in an anticompetitive scheme to block generic competition for Suboxone -- thereby continuing to obtain monopoly profits from the drug at the expense of purchasers.

Reckitt Benckiser Pharmaceuticals (Reckitt), now known as Indivior, is accused of conspiring with defendant MonoSol Rx to switch branded Suboxone from a tablet version to a film in order to prevent or delay generic alternatives and maintain Reckitt's monopoly profits. The lawsuit alleges that this conduct was illegal "product hopping," where a company makes modest changes to its product to extend patent protections so other companies cannot enter the market and offer cheaper generic alternatives.

"Our suit alleges that Reckitt attempted to profit from the opioid epidemic in our country by using unlawful, anti-competitive means," Attorney General Racine said. **"We believe these anti-competitive actions led to higher prices for purchasers of Suboxone, including the District -- making it more expensive for government entities to fight the growing crisis of opioid addiction our nation faces. That's why we've brought this action along with our colleagues from across the country."**

Suboxone is used to treat heroin addiction and other opioid addictions by easing addiction cravings. The lawsuit alleges that in 2002, when Reckitt introduced Suboxone in tablet form, it had seven years of exclusivity protection -- meaning no generic version could enter the market during that time. Before that period ended, however, Reckitt worked with MonoSol to create a new version of Suboxone as a dissolvable film, similar in size to a breath strip. Over time, Reckitt allegedly steered health professionals who prescribed Suboxone from

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the tablet to the film through marketing, price adjustments, and other methods. Ultimately, after the majority of Suboxone prescriptions were written for the film, Reckitt removed the tablet from the U.S. market. No generic alternative to the film is currently available.

The lawsuit alleges that Reckitt's "product hop" was anticompetitive, because the Suboxone film provided no real benefit over the tablet and Reckitt continued to sell the tablets in other countries even after removing them from the U.S. market. Reckitt also allegedly expressed unfounded safety concerns about the tablet version and intentionally delayed FDA approval of generic versions of Suboxone. The lawsuit alleges that the purpose of this conduct was to hinder the entry of generic alternatives to Suboxone and to illegally extend Suboxone's exclusivity through the switch to the film version.

The alleged result of defendants' conduct is that purchasers have paid artificially high monopoly prices since late 2009, when generic alternatives of Suboxone might otherwise have become available. During that time, annual sales of Suboxone topped \$1 billion.

The lawsuit, filed in the U.S. District Court for the Eastern Division of Pennsylvania, accuses the companies of violating the federal Sherman Act and state laws. Counts include conspiracy to monopolize and illegal restraint of trade. In the suit, the Attorneys General ask the court to stop the companies from engaging in anticompetitive conduct, to restore competition, and to order appropriate relief for states and the District as well as for the costs and fees for the attorneys general.

The Attorneys General of the following states joined in the lawsuit along with the District: Alabama, Alaska, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wisconsin.

A redacted copy of the lawsuit is attached. The complaint was filed under seal, as it contains information required to be kept confidential by federal and state law.

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